|  |  |  |  |
| --- | --- | --- | --- |
| **Meeting Purpose** | **DIA EDM Reference Model - Devices** | | |
| **Meeting Date** | 22.07.2015 | | |
| **Meeting Time** | 17:00 (CET) - Europe Time (Rome, GMT+01:00) | | |
| **Meeting Location** | Webex | | |
| **Meeting Facilitator** | Romuald Braun | | |
| **Meeting Attendees** | **Company** | **Name** |  |
|  | Infotehna | Eric Haase |  |
|  | Infotehna | Metod Ostanek |  |
|  | VRTX | Laura Sherman |  |
|  | Impact Systems | Cheryl Lewis |  |
|  | Fresenius Kabi | Christine Berger |  |
|  | Fresenius Kabi | Yong Liu |  |
|  | Navitas | David Gwyn |  |
|  | Premier Logic | Ty Molchany |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Discussions and Action Items** | | | | |
| **#** | **Topic Discussed** | **Discussion & Required Action  (if any)** | **Assigned To** | **Due Date** |
| 00 | Review of minutes and open topics from previous meeting |  | All |  |
| 02a.a |  | RPS vs. US 510k mapping  (see previous minutes from 21.May.2015) | Yong | Ongoing |
| 02c |  | Proposed artifact names should be unique regardless of its position within the model in order to avoid confusion. Check for duplicates should be performed. | All | Future |
| 02d |  | Proposed artifact names should be checked in the context of the authoring process. In case artifacts are in reality authored as several sub-artifacts and later compiled together, another level of sub-artifacts should be introduced to cover this scenario. | All | Future |
| 03 | Metadata matrix | Metadata mapping should be checked | All | Future |
| 04 | Terminology used in Reference Model | Suggestion to introduce additional column(s) for definition of terms – to standardise and to have common understanding. |  | Ongoing |
| 04a |  | Try to add additional columns and assess/discuss the complexity with the team | Metod | On hold (04b) |
| 04b |  | Review the Terms Definition section of the Quality Model to see, how it can be leveraged. It seems, terms need to be defined before continuing the work with following items:   * 02c * 02d * 03 * 04a * 09b * 10   Romuald will take the 1st look and suggest an approach leveraging the work done in Quality. | Romuald | Ongoing |
| 05 | How to improve the visibility of the team and the initiative. | Spread the info around – list of potential members / contributors | All | Ongoing |
| 05a |  | Approach medical devices forums and associations to test their motivation to join the Ref.Model initiative:   * IMDRF * ADVAMED * MEDTECHEUROPE   (See links below) | Romuald B.  In progress | Ongoing |
| 06 | Webex – technical issue with voice quality | dial-in option should be investigated | Romuald B. | Done |
|  |  | The VOIP quality seems to be OK. |  |  |
| 07 | Structure mapping between RPS nIVD and STED nIVD (TAB07) | Review the current mapping between RPS and STED (TAB 07) | Romuald U. | Ongoing |
| 08 | Consider IDMRF Consultations and Documents | Especially - Regulated Product Submission - Assembly and Technical Guide for IMDRF Table of Contents (ToC) Submissions (<http://imdrf.org/consultations/cons-rps-atg-imdrf-toc-150409.asp> ) |  | Future |
| 09a | Excel sheets | Question was raised whether it would be more convenient if the reference model sheets should be separated from the mapping sheets in order to have 2 leaner excel files. Steve’s opinion was to keep all the things in one sheet to facilitate consistency. |  | Done |
| 09b | Model mapping | Question was raised whether to use unique coding for each model (RPS codes should be used just for cross-reference and not as primary coding). When cross-checked with the Submission reference model, they don’t use specific coding and present CTD mapping on in the attributes section. |  | On hold  (04b) |
| 09b.a |  | Once we have the definition of terms, it will be used to create unique coding |  | On hold  (04b) |
| 10 | Artefacts meta data | Start to identify required meta data fields:   * Mandatory (M) * Optional (O) * Cardinality |  | On hold  (04b) |

|  |
| --- |
| **DIA EDM Reference Model – Devices: general info & References for RM:** |
| Web site for communication and exchange – <http://edmrefmodel.com/device-reference-model-team/> |
|  |
| **STED – Authoring Group: Study Group 1 of the Global Harmonization Task Force** |
| Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED), February 21, 2008 |
| <http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n011-2008-principles-safety-performance-medical-devices-080221.pdf> |
| Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices, March 17th, 2011 |
| <http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n063-2011-summary-technical-documentation-ivd-safety-conformity-110317.pdf> |
|  |
| **RPS – Authoring Group: Regulated Product Submissions Table of Contents Working Group, 2014** |
| Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC) |
| <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140630-rps-nivd-toc.pdf> |
| In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC) |
| <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140630-rps-ivd-toc.pdf> |
|  |
| **Medical Devices Forums and Associations** |
| International Medical Device Regulators Forum |
| <http://imdrf.org/index.asp> |
| Advanced Medical Technology Association |
| <http://advamed.org> |
| MedTech Europe |
| <http://www.medtecheurope.org> |
|  |